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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,040	02/19/2002	Allan Svendsen	6072.204-US	9347
25908	7590	02/24/2005	EXAMINER	
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,040

Applicant(s)

SVENDSEN ET AL.

Examiner

David J Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,16-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10,16-18 and 20-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

[2] Claims 1-10, 16-18, and 20-22 are pending in the application.

[3] Applicants' preliminary amendment to the claims, filed 2/19/2002, is acknowledged.

[4] Applicants' election of the species of Group i), claims 2-3, 17-18, and 20-22, drawn to the special technical feature of a method for producing a variant of a parent pullulanase having altered isoamylase activity, filed 10/26/2004, is acknowledged.

[5] Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

[6] The instant Office action is a supplemental restriction made in view of the following deficiencies in the restriction requirement of the Office action mailed 9/22/2004: 1) the restriction requirement appears to have been made according to US practice for applications filed under 35 U.S.C. 111(a), however, it is noted the application is filed under 35 U.S.C. 371 and the restriction should have been made as a lack of unity of invention; 2) claim 16 was not indicated as being pending and was omitted from the claim groupings in the Office action mailed 9/22/2004, however, the examiner can find no amendment canceling claim 16; 3) claim 4 should have been

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included in Group i) of the claim groupings in the Office action mailed 9/22/2004; and 4) the claim groupings do not appear to encompass all embodiments of the claimed invention, only two specific embodiments, namely, a method for producing a variant of a parent pullulanase having altered thermostability or isoamylase activity, however, it is noted that the claims encompass additional embodiments, *i.e.*, the claims are not limited to these two specific embodiments. In view of these deficiencies, a supplemental restriction is required for proper restriction of the claims.

[7] The examiner can find no statement that the computer readable form (CRF) of the sequence listing and paper copy thereof are identical. Without such a statement, the application fails to meet the requirements for sequence compliance. Applicants are requested to provide such documentation.

[8] The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 121 as follows: The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application.

Lack of Unity

[9] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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[10] In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 2 and 20-21, drawn to the special technical feature of a method for producing a variant of a parent pullulanase having altered pH dependent activity and optionally having altered thermostability, substrate cleavage pattern, specific activity of cleavage, substrate specificity such as isoamylase activity, and/or substrate binding.

Group II, claims 2, 4-10, and 20-22, drawn to the special technical feature of a method for producing a variant of a parent pullulanase having altered thermostability and optionally having altered pH dependent activity, substrate cleavage pattern, specific activity of cleavage, substrate specificity such as isoamylase activity, and/or substrate binding.

Group III, claims 2 and 20-21, drawn to the special technical feature of a method for producing a variant of a parent pullulanase having altered substrate cleavage pattern and optionally having altered pH dependent activity, thermostability, specific activity of cleavage, substrate specificity such as isoamylase activity, and/or substrate binding.

Group IV, claims 2 and 20-21, drawn to the special technical feature of a method for producing a variant of a parent pullulanase having altered specific activity of cleavage and optionally having altered pH dependent activity, thermostability, substrate cleavage pattern, substrate specificity such as isoamylase activity, and/or substrate binding.

Group V, claims 2-3, 16-18, and 20-21, drawn to the special technical feature of a method for producing a variant of a parent pullulanase having altered substrate specificity such as higher isoamylase activity, and optionally having altered pH dependent activity, thermostability, substrate cleavage pattern, specific activity of cleavage, and/or substrate binding.

Group VI, claims 2 and 20-21, drawn to the special technical feature of a method for producing a variant of a parent pullulanase having altered substrate binding and optionally having altered pH dependent activity, thermostability, substrate cleavage pattern, specific activity of cleavage, and/or substrate specificity such as isoamylase activity.

[11] The technical feature linking groups I-VI is a method for producing a variant of a parent pullulanase. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-VI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. In this case, methods for producing a variant of a parent pullulanase having altered pH dependent activity, thermostability, substrate cleavage pattern, specific activity of cleavage, substrate specificity such as isoamylase activity, and/or substrate binding were known in the art at the time of the invention, particularly methods using homology modeling. The technical feature of claims 1-10, 16-18, and 20-22 is a method for producing a variant of a parent pullulanase having an altered property, which is shown by e.g., Bisgard-Frantzen et al. (US Patent 6,265,197) and Kaneko et al. (US Patent 5,965,442) to lack novelty or inventive step, and does not make the special technical feature a contribution over the prior art.

[12] Claim 1 link(s) inventions I-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

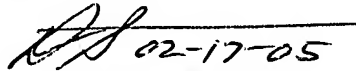
[13] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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[14] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[15] Claim 2 will be examined only to the extent the claim reads on the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday from 7:30 am to 5:00 pm and alternate Fridays from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

Handwritten signature of David J. Steadman, dated 02-17-05.

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER